UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. PHILIPS NORTH AMERICA LLC d/b/a PHILIPS MEDICAL SYSTEMS and PHILIPS HEALTHCARE, limited liability company, and CARLA KRIWET and OJAS A. BUCH, individuals, Defendants.	)	No. COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, brings this action under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"), 21 U.S.C. § 332(a), and alleges as follows:

INTRODUCTION

1. The United States seeks an injunction pursuant to 21 U.S.C. § 332(a) to stop Philips North America LLC, doing business as Philips Medical Systems and Philips Healthcare ("Philips"), and Carla Kriwet and Ojas A. Buch, individuals (hereafter collectively, "Defendants"), from:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, medical devices, within the meaning of 21 U.S.C. § 321(h), that are adulterated within the meaning of the Act, in that the methods used in, or the facilities or controls used for,

their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") requirements set forth in 21 C.F.R. Part 820; and

B. violating 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h), as described in paragraph A above, while such devices are held for sale after shipment of one or more of their components in interstate commerce.

2. The Food and Drug Administration ("FDA"), has repeatedly warned Philips that it has manufactured and distributed devices in violation of the statute. A permanent injunction is needed to prevent Defendants from violating 21 U.S.C. § 331(a) and (k).

JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

4. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

5. Defendant Philips North America LLC, a Delaware corporation, does business, *inter alia*, as Philips Medical Systems and Philips Healthcare, and is headquartered in Andover, Massachusetts. As a U.S. subsidiary of Royal Philips Electronics ("Royal Philips"), Philips designs, manufactures, and/or distributes articles of device, within the meaning of 21 U.S.C. § 321(h), at its facilities located at 3000 Minuteman Road, Andover, Massachusetts 01810 ("Andover facility"), and 22100 Bothell Everett Highway, Bothell, Washington 98021 ("Bothell facility") for Philips's Emergency Care & Resuscitation ("ECR") business unit of its Patient Care and Monitoring Solutions ("PCMS") business group. Specifically, Philips manufactures,

develops specifications, and distributes, among other things, external defibrillators, Q-CPR meters, electrocardiographs, ultrasound transducers, and patient monitors at or from the Andover facility, and external defibrillators at or from the Bothell facility.

6. Carla Kriwet is Business Group Leader for the PCMS business group within Philips. She has held this position since February 2015. She is responsible for, and has authority over, the quality of Philips's devices at the Andover and Bothell facilities. She directly reports to the Chief Executive Officer of Royal Philips.

7. Ojas A. Buch is Vice President, Head of Quality and Regulatory for the PCMS business group within Philips. He has held this position since March 2015. He is responsible for the quality of the PCMS devices at the Andover and Bothell facilities.

DEFENDANTS' DEVICES

8. Philips's products are devices, within the meaning of 21 U.S.C. § 321(h), in that they are intended (a) for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or (b) to affect the structure or any function of the body of man.

9. Philips distributes its devices in interstate commerce. For example, Philips has shipped its HeartStart MRx defibrillators to customers in New York and Pennsylvania. In addition, Philips receives components from outside Massachusetts and Washington and uses those components in the manufacture of its devices.

LEGAL STANDARDS

10. The Act authorizes FDA to "prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation . . ., packing, storage, and installation of a device conform to current good manufacturing practice, as

prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act." 21 U.S.C. § 360j(f)(1)(A). Pursuant to 21 U.S.C. § 360j(f), FDA has issued regulations setting forth CGMP requirements for devices in the Quality System Regulation, 21 C.F.R. Part 820 (hereafter, "QS regulation" or "QSR"). 21 C.F.R. § 820.1(a).

11. The failure to comply with any applicable QS regulation renders a device adulterated under 21 U.S.C. § 351(h). 21 C.F.R. § 820.1(c).

12. It is a violation of the Act to introduce or deliver for introduction into interstate commerce an adulterated device. 21 U.S.C. § 331(a).

13. It is a violation of the Act to do any act with respect to a device that causes the device to become adulterated while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. § 331(k).

DEFENDANTS' QSR VIOLATIONS AT THE BOTHELL FACILITY

15. FDA inspected Philips's Bothell facility between February 18 and April 21, 2015 ("April 2015 Bothell inspection"). This inspection revealed numerous violations of the Act and its implementing regulations. Specifically, FDA investigators documented Philips's failure to comply with the QS regulation including, but not limited to, the following:

A. Failure to establish and maintain adequate procedures for implementing Corrective and Preventive Action ("CAPA"), as required by 21 C.F.R. § 820.100(a). For example, Philips initiated a CAPA in response to complaints involving IRC R92 resistor failures during use of the HeartStart HS1 and FRx defibrillators, yet Philips's corrective actions were not adequate to fully address the problem with devices in the field and Philips continued to receive complaints about the failure;

B. Failure to establish and maintain adequate procedures to ensure that all purchased or otherwise received product conforms to specified requirements, as required by 21 C.F.R. § 820.50. For example, when Philips discovered that a supplier made an unapproved change to its cleaning process that led to contamination in Philips's patient cable assembly pin barrels, Philips directed its supplier to return to its original cleaning process but neither validated whether the previous cleaning process was implemented nor determined whether further corrective action was warranted despite documenting the same defect; and

C. Failure to validate software that was used as part of their quality system, as required by 21 C.F.R. § 820.70(i). For example, Philips did not validate that software used as a tool in risk evaluation operated in accordance with its intended use.

16. At the conclusion of the April 2015 Bothell inspection, FDA investigators issued a List of Inspectional Observations, Form FDA 483 ("Form FDA 483") to Philips detailing Philips's violations of the QS regulation.

DEFENDANTS' QSR VIOLATIONS AT THE ANDOVER FACILITY

17. FDA inspected Philips's Andover facility between April 27 and June 18, 2015 ("June 2015 Andover inspection"). This inspection also revealed numerous violations of the Act and its implementing regulations. Specifically, FDA investigators documented Philips's failure to comply with the QS regulation, including the following:

A. Failure to establish and maintain adequate procedures for implementing CAPA, as required by 21 C.F.R. § 820.100(a). For example, Philips initiated a CAPA in response to complaints describing injuries observed after use of Philips's Q-CPR meter, a device that provides feedback on chest compressions during cardiopulmonary resuscitation ("CPR").

Philips addressed this issue by adding supplemental language on the label of devices intended for future distribution that described how the adhesive pad should be used and stated that chest injuries could occur following CPR, but took no further steps to address the complaints regarding injury when the adhesive pad was used or the reports stating that the injuries were much more severe than typical;

B. Failure to establish and maintain adequate procedures for design verification, as required by 21 C.F.R. § 820.30(f). For example, Philips did not investigate and resolve a test failure when verifying a change to a battery used in the HeartStart MRx defibrillator, and did not accurately record other required information prior to approving such change in its verification report;

C. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 C.F.R. § 820.30(i). For example, Philips failed to investigate two change requests that were part of a battery change verification report; and

D. Failure to establish and maintain procedures for validating the device design to ensure that devices conform to defined user needs and intended uses, as required by 21 C.F.R. § 820.30(g). For example, Philips's instructions for use for its Q-CPR meter contradicted the instructions for use of its supplier by stating that customers should attempt to clean the vent membrane. Philips did not provide documentary evidence that showed Philips considered and reconciled the labeling differences.

18. At the conclusion of the June 2015 inspection, FDA investigators issued a Form FDA 483 to Philips detailing Philips's violations of the QS regulation.

PRIOR FDA INSPECTIONS

19. FDA previously inspected Philips's previous facility located at 2301 5th Avenue, Suite 200, Seattle, Washington, between April 5, 2010 and August 9, 2010 ("August 2010 Bothell inspection"), and the current Bothell location in August 2012 and April 2013.

20. FDA investigators observed and documented similar violations of the QS regulation including the following: design controls (21 C.F.R. § 820.30); purchasing controls (21 C.F.R. § 820.50); process controls (21 C.F.R. § 820.70); corrective and preventative action (21 C.F.R. § 820.100); and complaint handling (21 C.F.R. § 820.198).

21. At the conclusion of each of the 2010, 2012, and 2013 inspections, the FDA investigators issued a Form FDA 483 detailing Philips's violations of the QS regulation.

22. FDA previously inspected Philips's Andover facility between September 5, 2013 and December 12, 2013 ("December 2013 Andover inspection"). This inspection revealed numerous deviations from the QS regulation, including the following: design controls (21 C.F.R. § 820.30) and corrective and preventative action (21 C.F.R. § 820.100).

23. During inspections in January–March 2009 and October–December 2010 at Philips's Andover facility, FDA investigators observed and documented violations of the QS regulation including, but not limited to, violations involving the following: design controls (21 C.F.R. § 820.30); process controls (21 C.F.R. § 820.70); corrective and preventative action (21 C.F.R. § 820.100); and complaint handing (21 C.F.R. § 820.198).

24. At the conclusion of the March 2009, December 2010, and December 2013 Andover inspections, FDA investigators issued a Form FDA 483 to Philips detailing its violations of the QS regulation.

NOTICE OF VIOLATIONS

25. FDA has given Philips ample notice that it is manufacturing and distributing devices in violation of the Act and its implementing regulations. In addition to issuing Forms FDA 483 and discussing the observations with Philips, FDA sent Philips a recidivist Warning Letter, dated March 28, 2011, stating that Philips's devices were adulterated because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the CGMP requirements of the QS the regulation. The Warning Letter notified Philips that failure to correct these deviations could result in further regulatory action, including an injunction.

26. On June 7, 2013, FDA representatives met with Philips's representatives to discuss the company's corrective actions to the deviations identified during the April 2013 Bothell inspection. Philips's representatives discussed actions taken to hire new employees and to train existing employees.

27. On April 6, 2015, FDA representatives met with Philips's representatives to discuss the IRC R92 resistors and FDA's concerns about the company's risk analysis, as well as the adequacy of the supplemental information sheets distributed to Philips's customers and the recall.

28. FDA also sent Philips a Warning Letter, dated October 9, 2009, stating that the devices manufactured at the Andover facility were adulterated because the methods used in, or

the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the CGMP requirements of the QS regulation. The Warning Letter also notified Philips that failure to correct these deviations could result in further regulatory action, including an injunction.

29. On April 28, 2010, FDA met with Philips representatives. The Philips representatives discussed corrective actions at Philips's Andover facility, including organizational changes and changes to their policy for corrective actions. FDA warned them that the agency would consider further enforcement action if it continued to find problems.

30. In addition, after FDA investigators observed violations of the QS regulation during the 2010 Andover inspection, FDA met with Philips's representatives on March 10, 2011, to discuss the violations observed and the corrective actions at the Andover facility. The Philips's representatives promised corrections and explained that they were attempting to implement a common quality base for all Philips locations.

31. On April 4, 2014, FDA representatives met with Philips's representatives to discuss the December 2013 Andover inspection. FDA explained the agency's concerns about the CAPA and design violations observed during the inspection, and Philips's representatives discussed their corrective actions, including the firing of employees, a two-hour shut down at the facility, audits, and product recalls.

32. On March 11, 2015, FDA representatives met with Philips's representatives to discuss new organizational changes at Philips and their response to the December 2013 inspection observations. FDA expressed the agency's concerns about Philips's lack of a systemic approach in addressing the violations.

33. Although Philips has acknowledged some deficiencies regarding compliance with the QS regulation and promised corrective action, Defendants' responses to date do not adequately address the violations observed.

34. Accordingly, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any and all of the following acts at or from Philips's facilities located at 3000 Minuteman Road, Andover, Massachusetts 01810, 22100 Bothell Everett Highway, Bothell, Washington 98021, and any other locations at which Defendants now or in the future directly or indirectly design, manufacture, process, pack, repack, label, hold, and/or distribute devices in its ECR business unit:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any device that is adulterated within the meaning of 21 U.S.C. § 351(h); and

B. violating 21 U.S.C. § 331(k), by causing any device to become adulterated within the meaning of 21 U.S.C. § 351(h), while such article is held for sale after shipment of one or more of its components in interstate commerce.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active

concert or participation with any of them, to cease directly or indirectly designing, manufacturing, processing, packing, repacking, labeling, holding, and/or distributing, any devices in its ECR business unit at or from Philips's facility located at 3000 Minuteman Road, Andover, Massachusetts 01810, and 22100 Bothell Everett Highway, Bothell, Washington 98021, and any other locations at which Defendants now, or in the future, directly or indirectly design, manufacture, process, pack, repack, label, hold, and/or distribute such devices, unless and until Defendants' methods, facilities, and controls used to design, manufacture, process, pack, repack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the QS regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA.

III. That the Court authorize FDA, pursuant to this injunction, to inspect Philips's facilities located at 3000 Minuteman Road, Andover, Massachusetts 01810, and 22100 Bothell Everett Highway, Bothell, Washington 98021, and any other locations at which Defendants now, or in the future, directly or indirectly design, manufacture, process, pack, repack, label, hold, and/or distribute any devices within the PCMS business group, to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Respectfully submitted,

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